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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,951	09/10/2003	Todd Allen Berg	293/029Cont3	5856

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FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/659,951	Applicant(s) BERG ET AL.	
	Examiner Michael Thaler	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dakov (6,030,392). Dakov, in figures 30-33, discloses an apparatus for cutting an aperture in a side wall of a blood vessel comprising a tissue-piercing structure 406, a plurality of structures (the barbs at 408) mounted on the tissue-piercing structure and tissue-cutter structure 410. The tissue-cutter structure 410 is configured for rotation about the longitudinal axis of the tissue piercing structure for two independent reasons. First, the entire apparatus shown in figures 30-33 (including the tissue-cutter structure and the tissue-piercing structure) is clearly inherently configured for rotation about the longitudinal axis of the tissue piercing structure, by for example, manually rotating the entire apparatus about that axis. Second, (and in regard to claim 6) the tissue-cutter structure 410 is freely slidable over the rod 402 in both the longitudinal and circumferential directions as

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evidenced by the absence of any structure on the outer surface of rod 402 which would prevent such movement (noting the smooth outer surface of the upper and middle portion of rod 402 in figure 32 and the smooth outer surface of the lower portion of rod 402 in figures 30, 31 and 33). The Dakov specification fails to specifically state that the barbs 408 are resilient as claimed. However, figure 30 shows the barbs spread radially outwardly from shaft 406. Further, it is clear that the barbs are compressed radially inwardly when they pass through the wall of organ 414 since figures 31 and 33 show the puncture opening in organ 414 as being small as compared to the lateral extent of the barbs in figure 30. Further, it is clear that the barbs expand radially outwardly once they are within organ 414 since the cutout portion 416 is described as being mounted on the barbs as the instrument is withdrawn in col. 14, lines 11-13. Since the barbs apparently expand radially outwardly once the compressive force on them is removed, it would have been obvious that they are resilient as claimed. As to claim 8, the distal portion of tissue-piercing structure 406 is configured to deflect transversely after passing through the side wall, as broadly claimed, since it is made of thin wire-like material as shown in the drawings and thus is inherently capable of being bent transversely (at least slightly) once it has passed through

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the side wall and, for example, contacts the opposite side wall of the organ to deflect it transversely.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dakov (6,030,392) in view of van der Gaast (3,577,979). As to claim 1, assuming *arguendo* that the Dakov tissue-cutter structure 410 is not configured for rotation about the longitudinal axis of the tissue piercing structure, van der Gaast teaches that a circular cutting edge of a surgical punch should be rotated as it is advanced in order to obtain the advantage of reducing tearing of the tissue (col. 2, lines 35-39). It would have been obvious to configure the Dakov tissue-cutter structure 410 for rotation so that it too would have this advantage. As to claim 7, Dakov fails to disclose the cutting edge 412 as being serrated. However, van der Gaast teaches that a circular cutting edge of a surgical punch should be serrated in order to obtain the advantage of reducing tearing of the tissue (col. 2, lines 35-39). It would have been obvious to make the Dakov cutting edge 412 serrated so that it too would have this advantage.

Claims 1-6 and 8-11 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kornberg et al. (5,353,804). Kornberg et al. in figures 1-8, disclose a tissue-piercing structure (the distal

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portion of 23), a plurality of structures (the barbs at 24) mounted on the tissue-piercing structure and tissue-cutter structure 2 (col. 8, lines 23-27. The Kornberg et al. apparatus is inherently capable of cutting an aperture in a side wall of a blood vessel since tissue-cutter structure 2 has a sharp edge 5. Alternatively, it would have been obvious that the Kornberg et al. apparatus is capable of cutting an aperture in a side wall of a blood vessel since tissue-cutter structure 2 has a sharp edge 5. The tissue-piercing structure is inherently capable of passing through all of the tissue to be pierced without any external means of support. For example, the tissue-piercing structure (a short distal portion of 23), is inherently capable of first being pushed beyond the distal end of needle 20 and then pushed into tissue. Evidence to support this assertion is that the distal portion of 23 is disclosed by Kornberg et al. as being sufficiently strong, rigid and sharp to penetrate the tissue when it is extended out of the needle 20 where it no longer has any external support from the needle as described in col. 7, lines 41-44. As to claim 8, the distal portion of tissue-piercing structure is configured to deflect transversely after passing through the side wall, as broadly claimed, since it is made of thin resilient material and thus is inherently capable of being bent transversely (at least slightly) once is

has passed through the side wall and, for example, contacts the opposite side wall of the organ to deflect it transversely.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg et al. (5,353,804) in view of van der Gaast (3,577,979). Kornberg et al. fail to disclose the cutting edge 5 as being serrated. However, van der Gaast teaches that a rotating circular cutting edge of a surgical punch should be serrated, at 30, in order to obtain the advantage of reducing tearing of the tissue (col. 2, lines 35-39). It would have been obvious to make the Kornberg et al. cutting edge 5 serrated so that it too would have this advantage.

Applicant's arguments filed Sep. 10, 2003 have been fully considered but they are not persuasive. Although Dakov discloses other instruments having different shapes (col. 14, lines 14-15), the instrument 400 shown in the drawings has a circular shape. Rotation of the cutter 410 of this instrument 400 would not render it inoperable since it is circular. It should be noted that the claimed "tissue-piercing structure" (claim 1, line 3) is considered to be only the distal portion of wire 30 of applicant's invention (i.e. the portion of wire 30 which extends beyond the distal end of sheath 20 during tissue piercing). This is because there is no disclosure in applicant's specification that the main portion of wire 30 (i.e.

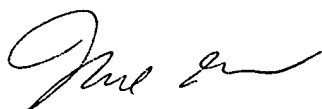
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the portion within sheath 20) does not contact the surrounding sheath 20 at any point and thus receive support therefrom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

mht



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731